JUUL Labs, Inc.'s Responses to Questions for the Record

Committee on Energy & Commerce
Subcommittee on Oversight & Investigations

Hearing on
"Vaping in America: E-Cigarette Manufacturers' Impact on Public Health"

February 5, 2020

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INTRODUCTION

On behalf of JUUL Labs, Inc. (JLI or the Company), we are pleased to respond to specific questions raised by Subcommittee members for the record. As context for our responses, we offer the following background and introduction.

As our CEO, K.C. Crosthwaite, expressed in his testimony, we recognize that JLI and the category in general stand at a critical inflection point. Trust in our company and category has eroded in recent years, and we must continue to work to reverse the trend in underage use of electronic nicotine delivery system (ENDS) products. We also continue to believe that our fundamental purpose — to accelerate the decline of combustible cigarettes among adult smokers — is as urgent as ever. Despite tobacco-control measures implemented over the last several decades, use of combustible cigarettes remains the leading cause of preventable death here and abroad, contributing to approximately 480,000 deaths each year in the United States alone.

Against that backdrop, we believe the dialogue fostered by this Subcommittee and the full Committee on Energy & Commerce is necessary and vitally important. We hope the testimony provided by Mr. Crosthwaite was constructive as the Committee continues to evaluate public policy aimed at protecting American youth from access to ENDS products, while at the same time preserving the public-health opportunity for adult smokers to transition from combustible cigarettes to less harmful noncombustible alternatives.

We also would like to reaffirm the commitment that Mr. Crosthwaite made in his testimony: Our company is keenly focused on resetting our relationships with stakeholders and re-earning their trust. Key to that effort is the ongoing work to prepare our Premarket Tobacco Product Application (PMTA) for FDA's review, which we will submit by the May 2020 deadline.

The science- and evidence-based PMTA process will evaluate whether JUUL products are appropriate for the protection of public health. This includes considering both the ability of JUUL products to switch adult smokers from combustible cigarettes to potentially less harmful products and the Company's ability to restrict initiation among nonusers, especially those who are underage. Our team is working hard to finalize our application, which we believe will be scientifically rigorous, substantively robust, and ultimately compelling.

QUESTIONS AND RESPONSES

The Honorable Frank Pallone, Jr. (D-NJ)

1. In its October 17, 2019 press release, JUUL announced it would suspend sales of "non-tobacco, *non-menthol-based* flavors (Mango, Creme, Fruit, and Cucumber) in the U.S." (emphasis added). Mint is not specified as a distinct flavor in the October press release, and the additional suspension of sales of JUUL's mint products was not announced until several weeks later, on November 7, 2019. Since JUUL did not include its mint products within its suspension of sales of "non-menthol-based flavors," does JUUL consider its mint product to be a menthol-based flavor? How, if at all, does JUUL's mint products (not currently being marketed in the United States) differ from its menthol products, which remain available for sale in the United States?

Response: Since 2018, JLI has taken a number of significant, voluntary steps to address the increase in underage use of ENDS products, including JUUL products. More recently, in November 2019, following the release of data from the annual Monitoring the Future (MTF) survey, we stopped the sale and distribution of Mint flavored JUUL products, thus limiting our U.S. commercial portfolio to tobacco and menthol flavors only.

Data from the 2019 MTF survey revealed greater use of Mint among 10th and 12th graders compared to other flavored JUUL products. Among 12th graders who used JUUL products within the past thirty days, 47.1% used Mint most often.[1] Among 10th graders, the number was 43.5%.[2] Such results, coupled with the broader increase in underage use of ENDS products from 2018 to 2019, necessitated swift and serious action, if we were to preserve the harm-reduction potential of these products for adult smokers. Accordingly, as when JLI previously and voluntarily stopped the sale of certain flavored JUUL products, we ceased selling Mint and committed to not reintroducing any other flavored product unless and until it went through FDA's premarket-review process.

Historically, menthol and mint flavors in tobacco and other nicotine products have been classified as having a similar characterizing flavor based on the taste and aroma experienced by the user. For example, the menthol flavor in combustible cigarettes often has been characterized as having a "minty" taste and aroma. In the 2011 report from the Tobacco Products Scientific Advisory Committee (TPSAC) relating to the public-health impacts of menthol cigarettes, it noted throughout that "menthol produces a minty taste and aroma."[3]

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[1] *See* A. Leventhal, PhD., et al, Research Letter: Flavors of e-Cigarettes Used by Youths in the United States, Journal of American Medical Association (Nov. 5, 2019).

[2] *See id.*

[3] Tobacco Products Scientific Advisory Committee, Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, 17 (2011); *see also*, FDA, Menthol and Other Flavors in Tobacco Products, https://www.fda.gov/tobacco-products/products-ingredients-components/menthol-and-

Menthol and mint also have been grouped together in various surveys that assessed tobacco-use patterns relating to flavors for both youth and adults. The National Youth Tobacco Survey (NYTS), in asking "[w]hat flavors of tobacco products have you used in the past 30 days," maintains "Menthol or mint" as one flavor category, compared to others such as "Clove or spice," "Fruit," "Chocolate," and "Candy desserts or other sweets."[4] In the Population Assessment of Tobacco and Health (PATH) Study, questions regarding flavor choice and ENDS use identify "Menthol or mint" as a category, while distinguishing from others such as "Tobacco-flavored," "Clove or spice," "Fruit," and "Chocolate."[5] In understanding the impact of flavors among adults and youth through research, menthol and mint typically have been grouped together, presumably given the perceived similarities in sensory attributes.

The historical grouping of menthol and mint — when describing the characterizing flavor of a tobacco product — was a consideration for differentiating "tobacco and menthol-based flavors" from "non-tobacco and non-menthol-based flavors" for JUUL products. For the latter, JLI stopped their sale to traditional retail in November 2018, and then stopped their sale on the Company's age-restricted, 21+ e-commerce platform in October 2019.

Regardless of this categorical approach or classification, our Menthol and Mint products are quite different. While both contain menthol flavor ingredients, they comprise different flavor extracts and present different sensory profiles. The Mint JUUL product includes mint- and menthol-based flavor ingredients, in contrast to the Menthol JUUL product, which contains primarily tobacco- and menthol-based flavors. Each presents a different sensory profile that would be experienced and noticed by users.

As noted above, we currently market only JUUL products in Virginia Tobacco, Classic Tobacco, and Menthol flavors and will not reintroduce any other flavored product unless and until it goes through FDA's premarket-review process.

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other-flavors-tobacco-products ("Menthol is a flavor addictive with a minty taste and aroma . . . .") (last accessed Mar. 5, 2020).

[4] *See* CDC, National Youth Tobacco Survey, Questionnaire, Question 62 (2019). Moreover, in Question 13 relating to whether the respondent has smoked menthol cigarettes in the past 30 days, it notes that "[m]enthol cigarettes are cigarettes that taste like mint."

[5] *See, e.g.*, Population Assessment of Tobacco and Health Study, Wave 4: Adult Questionnaire (English Version) (2018).

The Honorable Diane DeGette (D-CO)

1. Do you expect that the guidance issued by the Food and Drug Administration (FDA) on January 2, 2020, and in effect as of February 6, 2020, will reduce youth use of JUUL's products or of e-cigarette products in general? Why or why not?

Response: Yes. JLI believes that FDA's January 2020 final guidance on enforcement priorities for certain ENDS products, coupled with legislation raising the minimum-purchasing age to 21 (Tobacco 21), should reduce underage use across ENDS products, if fully enforced. These two measures represent a critical reset of the ENDS category; a reset needed to preserve the harm-reduction potential of these products for adult smokers which is jeopardized by underage use. Taken together, they serve as a major step toward restricting access, appeal, and ultimately use of ENDS products among those who are underage. We unequivocally support both actions.

FDA's final guidance stands as a comprehensive near-term approach to address a market that has resulted in increases in underage use of ENDS products. Enforcement is imperative. And as of the date of this response, FDA has issued twenty-two Warning Letters to manufacturers and retailers (both brick-and-mortar and online) for selling non-tobacco- and non-menthol-flavored, cartridge-based ENDS products contrary to the policy set forth in the final guidance.[6] This enforcement action included sixteen major retailers from across the country, presumably as part of a broader focus on compliance inspections. Moreover, as of February 19, 2020, soon after the final guidance became effective, FDA issued an import alert for violative products, to help stem the inflow of illegal products entering the United States from foreign manufacturers.[7]

FDA's guidance also extends beyond just non-tobacco- and non-menthol-flavored, cartridge-based ENDS products. Indeed, any ENDS manufacturer or product — regardless of the type or flavor — will be subject to enforcement action if the product continues to be sold or marketed to minors.[8]

For example, regardless of the product type or flavor, FDA will prioritize enforcement against *any* manufacturer that fails to take adequate measures to prevent underage access. Necessarily, responsible manufacturers should be driven to enact and enforce more comprehensive retailer-compliance policies, including "secret shops" to ensure age-verification compliance and other sales restrictions, including product-quantity limits to reduce social sourcing. Retailers are at the front lines of preventing underage

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[6] *See* FDA, Enforcement Actions against Illegally Marketed Tobacco Products, https://www.fda.gov/tobacco-products/ctp-newsroom/enforcement-actions-against-illegally-marketed-tobacco-products (last accessed Mar. 10, 2020).

[7] *See* FDA, Import Alert 98-07, available at https://www.accessdata.fda.gov/cms_ia/importalert_1164.html.

[8] *See* FDA, Guidance for Industry, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market without Premarket Authorization, 21–27 (Jan. 2020) (hereinafter, "FDA Guidance on Enforcement Priorities").

access to all tobacco products, including ENDS, but bad actors that repeatedly fail to comply with age-verification laws should not be able to carry such products.

In addition, manufacturers should be incentivized to work with retailers and other industry stakeholders to promote and adopt advanced age-verification technologies to verify age and ID validity at the point-of-sale. Retail technology has evolved over the last several years, and, as an example, retailers now can incorporate electronic ID scanners into existing point-of-sale systems to automatically ensure purchasers are at least 21 years of age before completing the transaction.

Since 2019, JLI has been working with its retailer partners to implement these technologies through a standards-based point-of-sale (POS) program. This program enables retailers to update their POS system to automatically block the purchase of JUUL products unless the retail salesclerk scans a government-issued ID to verify age (21+) and ID validity (within expiry). The POS update also automatically limits the amount of JUUL products that may be purchased to reduce the potential for social sourcing (i.e., buying excess products and sharing or reselling them with minors).[9]

As another example, regardless of the product type or flavor, FDA will prioritize enforcement against *any* ENDS product that is targeted to minors or whose marketing is likely to promote use by minors. As FDA noted, "[m]any ENDS products have been and continue to be marketed to minors through a variety of media and technology, and their labels and labeling, print advertising, and/or online advertising are appealing to minors."[10]

FDA specifically outlined examples of ENDS product marketing that would be a focus for enforcement:

- Labeling and/or advertising that resemble kid-friendly foods and drinks or resemble other non-ENDS products that are often marketed and/or appealing to youth;

- Promoting ease of concealing the product or the nature of the product as a tobacco product from parents, teachers, or other adults;

- Marketing with youth-appealing cartoon or animated characters, such as those that depict or resemble popular children's characters;

- Marketing through paid social media influencers, with popular children's characters and titles.[11]

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[9] Additional information about JLI's standards-based POS program for retailers of JUUL products is discussed below in response to Ranking Member Guthrie's Question 2.

[10] FDA Guidance on Enforcement Priorities, at 24.

[11] *Id.* at 26–27.

Well before the final guidance was issued, FDA had taken a number of enforcement actions against manufacturers that were marketing their products to resemble kid-friendly foods and drinks. In November 2018, FDA issued a Warning Letter against one manufacturer for selling nicotine-containing e-liquids in packaging that resembled, among other products, "Cinnamon Toast Crunch," "Lucky Charms," "Rice Krispies Treats," "Froot Loops," and "Unicorn Cakes."[12] FDA and FTC jointly took similar actions against manufacturers in April 2018 and August 2018, respectively.[13] We anticipate such enforcement actions to continue, with even greater focus now, against manufacturers that are deliberately marketing their products to appeal to minors.

JLI, on the other hand, has significantly scaled back its marketing voluntarily. In September 2019, we suspended product advertising through broadcast (television and radio), print, and digital channels, and the Company exited social media for promotional purposes in November 2018. Currently, JLI markets only through retail channels (where combustible cigarettes are typically sold), direct-to-consumer promotional communications in which the recipient has been verified as at least 21 years of age, and on its website (JUUL.com). These marketing materials, including the labeling for JUUL products, have been tailored to adult smokers to communicate JUUL products as an alternative to cigarettes to transition them from combustible use.

While the final guidance outlines FDA's enforcement priorities for certain ENDS products, including flavor restrictions, it does not apply to illegally marketed, non-deemed products. Regardless of the type or flavor, products that came to the market after August 8, 2016, without premarket authorization are subject to enforcement immediately. Such products marketed outside of FDA's compliance policy do not get the benefit of any safe harbors provided by the final guidance. Specifically, certain single-use, disposable products that have gained popularity among minors — including Puff Bar, STIG, and Eonsmoke — likely came to the market after August 8, 2016, and are not subject to FDA's compliance policy for deemed products or the January 2020 final guidance.[14] That is, they likely are being marketed illegally.

Much discussion has focused on a footnote in FDA's final guidance that purportedly exempts "self-contained, disposable products" from its restrictions on flavors for cartridge-

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[12] *See* FDA, Warning Letter to Electric Lotus, LLC (Nov. 2018), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electric-lotus-llc-568710-11292018.

[13] *See* FDA, News Release, FDA, FTC Take Action against Companies Misleading Kids with E-liquids That Resemble Children's Juice Boxes, Candies and Cookies (April 2018), available at https://www.fda.gov/news-events/press-announcements/fda-ftc-take-action-against-companies-misleading-kids-e-liquids-resemble-childrens-juice-boxes; FDA, News Release, Companies Cease Sales of E-liquids with Labeling or Advertising that Resembled Kid-friendly Foods following FDA, FTC Warnings (Aug. 2018), available at https://www.fda.gov/news-events/press-announcements/companies-cease-sales-e-liquids-labeling-or-advertising-resembled-kid-friendly-foods-following-fda.

[14] *See, e.g.*, Associated Press, Young People Have Moved on to a New Kind of Vape Not Covered by the Flavor Ban: Disposables (Feb. 7, 2020).

based ENDS products.[15] JLI disputes this contention that somehow such new products entering the marketplace are exempt from FDA enforcement. Regardless of whether the product is "cartridge-based" or "disposable," the final guidance makes it explicitly clear that it — and the footnote on self-contained, disposable products — does not apply to products that came to the market after August 8, 2016, and lack premarket authorization.[16] Such products are illegal and subject to FDA's enforcement powers today.

In fact, FDA already has taken enforcement actions against these deeming violators over the last several months. For example, in October 2019, FDA issued a Warning Letter to Eonsmoke for illegally marketing nearly 100 flavored ENDS products without marketing authorization, among other violations.[17] These products in particular were designed and marketed to be "compatible" with JUUL products and were sold in such flavors as "Lush Ice," "Sour Gummy," "Peach Rings," and "Kiwi Strawberry." JLI believes FDA's enforcement against Eonsmoke compatible pods has helped clear them from the U.S. marketplace, and expects similar actions against other deeming violators, including manufacturers of single-use, disposable products like Puff Bar.

FDA also recently issued an import alert for "new tobacco products" entering the U.S. market without premarket authorization.[18] The issuance of this import alert is critical to detain and prevent the entry of non-deemed products that are being introduced by foreign manufacturers, often in a variety of kid-appealing flavors and packaging. It has the added effect of addressing the influx of illegal black-market products, including compatible products intended to look like another ENDS product that is no longer distributed and ENDS products intended for another country's market but diverted to the United States.

Critically, FDA's final guidance is buttressed by this Congress's passage of legislation raising the minimum-purchasing age for tobacco products, including ENDS, to 21. In a 2015 report, the Institute of Medicine concluded that raising the minimum-purchasing age for tobacco products "will likely prevent or delay initiation of tobacco use by adolescents and young adults" and have the greatest impact in reducing initiation among adolescents aged 15 to 17 years.[19] This conclusion stems, in part, from the fact that raising the age of legal access removes otherwise of-age purchasers (i.e., those who are 18 years old) from the

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[15] *See* FDA Guidance on Enforcement Priorities, at 9 n.9; *see also* Shelia Kaplan, Teens Find a Big Loophole in the New Flavored Vaping Ban, New York Times (Feb. 12, 2020).

[16] *See* FDA Guidance on Enforcement Priorities, at 2 n.2 ("As with FDA's prior compliance policies on deemed new tobacco products that do not have premarket authorization, this guidance does not apply to any deemed product that was not on the market on August 8, 2016."); *id.* at 3 ("This guidance does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization.").

[17] *See* FDA, Warning Letter to Eonsmoke, LLC (Oct. 2019), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/eonsmoke-llc-592097-10242019.

[18] *See* FDA, Import Alert 98-06, available at https://www.accessdata.fda.gov/cms_ia/importalert_1163.html.

[19] Institute of Medicine, Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products, S-3–S-4 (2015).

peer groups of younger adolescents (i.e., those who are 15–17 years old). JLI has long supported Tobacco 21 and believes this is a cornerstone piece in the overall strategy to combat underage uptake of tobacco products, particularly through social sourcing.

Social sourcing remains the main access point for underage use of all tobacco products and specifically for ENDS. Based on results from the 2019 NYTS, social sourcing (third-party resale or sharing) accounts for approximately 70% of use among high-school students and approximately 80% of use among middle-school students.[20] Among high-school current users of JUUL products, 63% obtained the product from a friend, 10% obtained the product from a family member, and 12.2% obtained the product from another person.[21] From the 2017 Youth Risk Behavior Survey (YRBS), only 13.6% of high-school students (aged 17 years or younger) obtained an ENDS product from a brick-and-mortar retail outlet, while 6.7% obtained an ENDS product online.[22] By raising the minimum-purchasing age to 21, older high-school students, who may vary from 18–19 years of age, should no longer be able to purchase any tobacco product, including ENDS, and then resell or share them with their younger peers.

We also believe it is necessary for states to continue passing Tobacco 21 legislation to align with the new federal requirement. By the time Congress passed the law in December 2019, nineteen states and Washington, D.C. had raised the minimum-purchasing age for tobacco products to 21, and several more states recently have enacted such legislation. Yet for states that have not, the apparent conflict within their local statutes prevents state enforcement authorities from penalizing retailers that continue to sell to those under 21 years of age. To ensure effective enforcement and facilitate retailer compliance across the country, JLI will continue supporting Tobacco 21 laws at the state level.

FDA's January 2020 final guidance, in addition to Tobacco 21, should have an impact in reducing underage use of ENDS products, including JUUL products. But we also do not expect these numbers to come down overnight. This requires a collective effort across stakeholders, including industry and public health, to work with regulators and policymakers to develop effective regulatory policies to prevent underage use, while preserving the public-health opportunity for adult smokers to provide them with a less harmful alternative to combustible cigarettes.

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[20] *See* CDC, National Youth Tobacco Survey (2019). The data largely track 2018 NYTS results as well, in which over 70% of underage use of ENDS came from social sources. *See* CDC, National Youth Tobacco Survey (2018).

[21] *See* CDC, National Youth Tobacco Survey (2019).

[22] *See* CDC, Youth Risk Behavior Survey (2017).

2. Do you believe FDA or other federal agencies have the resources (financial or otherwise) to monitor data and evolving trends with respect to youth use of e-cigarettes? If not, what more needs to be done?

Response: While JLI does not have particular insight into the adequacy of FDA or other federal agency funding, we believe that government-sponsored surveys, in addition to third-party research, on tobacco-use behaviors among those underage are imperative to develop effective, data-driven tobacco-control strategies to reduce underage use. Currently, the Federal Government conducts or supports at least four annual or periodic surveys relating to tobacco use among minors: NYTS, YRBS, Youth Tobacco Survey (YTS), and PATH. While in varying formats, each of the research programs helps shed light on the prevalence of tobacco use among minors, frequency of use, types of product use, and reasons for such use. From that, regulators, public health, industry, and other stakeholders not only have a better understanding of trends in tobacco use among those who are underage, but also how to develop effective measures to address core drivers of such use like product access and product appeal.

These surveys have been informative of tobacco-use trends over time, but given inherent constraints in their design, execution, and reporting, the data often provide only a retrospective snapshot of a rapidly evolving marketplace of tobacco and nicotine products. There may be supplemental research programs or surveys that could provide more frequent, real-time data to identify specific use causes and inform targeted underage-prevention measures. One example would be a quarterly online, longitudinal study that tracks use patterns over a year and specifically identifies which products are being used, how they are being accessed, and where minors are being exposed to these products (through marketing or otherwise).[23]

The current work that CDC and FDA do through the NYTS and other surveys is critical to understand the trends in tobacco use among minors, how they are accessing these products, and why they are using them to develop informed tobacco-control policies. JLI has no reason to believe resources (financial or otherwise) are an immediate issue, but we believe that all stakeholders, including federal agencies, public health, and other research institutions, should evaluate additional research tools to provide more refined and responsive data to combat underage use.

[23] On January 23, 2020, CDC opened a public docket to request comments on activities relating to the NYTS for 2021–2023. JLI intends to submit a comment to provide insights on potential opportunities to enhance the NYTS to inform effective tobacco-control strategies.

The Honorable Brett Guthrie (R-KY)

1. Currently, the Food, Drug and Cosmetic Act limits the ability of the U.S. Food and Drug Administration (FDA) to disclose receipt of premarket tobacco product applications (PMTA).

a. After May 12, 2020, what is your understanding of how distributors, retailers, and other relevant entities will be able to determine which products have a PMTA submitted to FDA, and thus can remain on the market while under review, and which products do not have a PMTA submitted to FDA?

b. Are any regulatory or legislative changes necessary to help inform the public and enforcement authorities about which products will be allowed on the market after May 12, 2020?

Response: The premarket-review process for new tobacco products, including PMTAs, is foundational to a regulatory infrastructure that will enable alternative, less harmful products to enter the market for current users, when supported by the science and data. Congress's passage of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) ensures robust, science-based oversight by FDA of tobacco products, while shepherding the entry of innovative, alternative forms of nicotine delivery for adult smokers without the combustion that causes the death and disease associated with cigarette use. We fully support the PMTA process as a necessary regulatory control for public health and look forward to submitting our applications by May 2020 and beyond.

During this transitionary period, where currently marketed products will be subject to premarket review through the submission of PMTAs by May 12, 2020, we agree that disclosure and transparency are needed. It is critical that distributors, retailers, consumers, and other stakeholders understand which products are subject to submitted PMTAs and thus are being marketed in compliance with FDA policy. This will help those same stakeholders know which products are being marketed illegally because the manufacturer either has not submitted a PMTA for the deemed product or otherwise has not obtained marketing authorization.

We believe there are a few options to provide transparency on the PMTA-review process during this transitionary period, including the legal disclosure of submitted PMTAs for deemed products that already have been on the market.

First, we believe, consistent with the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Tobacco Control Act, FDA may publish a list of PMTAs under review by the Agency for deemed products that were on the market as of August 8, 2016, along with the names of the corresponding products and manufacturers (hereinafter, "PMTA list for deemed products").

While the FDCA prohibits the public disclosure of "[a]ny information reported to or otherwise obtained by" FDA in a PMTA that is exempt from disclosure under Exemption 4

of the Freedom of Information Act (FOIA),[24] the PMTA list for deemed products does not fall within this exemption. Exemption 4 exempts from public disclosure records that are "trade secrets and commercial or financial information obtained from a person and privileged or confidential."[25] As FDA has explained, it considers the existence of a PMTA to be confidential commercial information under Exemption 4 when the applicant has not "publicly disclosed or acknowledged that it has submitted the application to FDA" and public disclosure therefore would prematurely reveal the manufacturer's "intent to market a tobacco product" and "could result in a competitive advantage to competitors."[26]

In the case of deemed products that have been on the market as part of this transitionary period (i.e., since at least August 8, 2016), the manufacturer's intent to market the product already is public and well-known. Moreover, for such products to be lawfully marketed after May 12, 2020, they must be the subject of a PMTA (or, if applicable, a Substantial Equivalence Report) and, therefore, public disclosure of a pending submission after the May deadline would not reveal any information that is not already publicly available. Unlike PMTAs for products that have not yet been marketed, disclosing the existence of PMTAs filed by manufacturers for deemed products on the market since at least August 8, 2016, would not reveal confidential commercial information.

Second, if for some reason the above is interpreted as inconsistent with the FDCA, FDA instead could publish a list of currently marketed deemed products for which PMTAs have not been submitted by the May 12, 2020 deadline, including the brand and product names, along with the corresponding names of the manufacturers. Such a list would not reveal confidential commercial information for the reasons outlined above.

In addition, such a list would reveal only a manufacturer's failure to meet a premarket-application requirement for a specific marketed product, which is information that FDA routinely discloses for products subject to premarket review. For example, FDA regularly issues Warning Letters to manufacturers for products marketed as drugs that are not subject to an approved new drug application, identifying the names of the manufacturers, brands, and specific products.[27] As noted above, FDA already has issued twenty-two Warning Letters to manufacturers and retailers (both brick-and-mortar and online) for selling non-tobacco- and non-menthol-flavored, cartridge-based ENDS products in violation of the final guidance. These Warning Letters also identify the names of manufacturers, brands, and specific products.

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[24] 21 U.S.C. § 387f(c).

[25] 5 U.S.C. § 552(b)(4).

[26] *See* Proposed Rule, Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. at 50566, 50624–25 (Sept. 25, 2019).

[27] FDA, FDA Actions to Remove Unapproved Drugs from the Market by Company, https://www.fda.gov/drugs/enforcement-activities-fda/fda-actions-remove-unapproved-drugs-market-company (last accessed Mar. 13, 2020).

Moreover, FDA routinely publishes lists identifying specific products that lack required FDA approval or marketing authorization, as well as the names of the manufacturers of such products.[28] Similarly, the Agency maintains a list of tobacco products that are subject to "not substantially equivalent orders" (NSE orders) and, therefore, must be removed from the market, identifying the name of the product as well as the corresponding name of the manufacturer to, among other things, "help retailers identify NSE tobacco products that may be in their stores."[29]

Third, manufacturers themselves should issue a communication (e.g., press release) that informs the public they have submitted a PMTA for a deemed product as of the May 12, 2020 deadline. Manufacturers of FDA-regulated products are authorized to voluntarily disclose information about the regulatory status of products, including when the manufacturer submits a premarket application to the Agency.[30] During this transitionary period, where currently marketed deemed products have been on the market since at least August 8, 2016, and are now subject to a PMTA submission deadline of May 12, 2020, manufacturers of these products should be proactive in informing distributors, retailers, consumers, and other stakeholders of their compliance with this important regulatory requirement.[31] Similarly, distributors and retailers should request such information from manufacturers as a condition precedent to carrying ENDS products after the May 12, 2020 submission deadline.

2. During the summer of 2018, FDA conducted an enforcement blitz of retailers nationwide, resulting in more than 1,100 Warning Letters and approximately 130 civil monetary penalties being issued to retailers for underage sale of e-cigarettes. Those cases included the illegal sale of Logic, JUUL, Fontem, and JTI products to minors. As such, each company received a letter from FDA in September 2018 requesting a meeting with FDA and that each company submit a detailed plan to address and mitigate widespread use by minors.

a. What was the result of your company's response to this request from FDA?

Response: In September 2018, then FDA Commissioner Scott Gottlieb sent a letter to the five largest manufacturers of ENDS products, including JLI, asking how they were going to

[28] *See, e.g.*, FDA, Questions and Answers for Consumers about FDA's Action Involving Unapproved Codeine Sulfate Tablets, https://www.fda.gov/drugs/unapproved-drugs/questions-and-answers-consumers-about-fdas-action-involving-unapproved-codeine-sulfate-tablets (last accessed Mar. 13, 2020).

[29] FDA, Misbranded and Adulterated NSE Tobacco Products, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/misbranded-and-adulterated-nse-tobacco-products#nseproducts (last accessed Mar. 13, 2020).

[30] *See, e.g.*, 84 Fed. Reg. at 50566, 50624–25; 21 C.F.R. §§ 314.430(b); 814.9(b)–(d).

[31] As a matter of course, manufacturers may issue a press release or otherwise publicly disclose the submission of a PMTA regardless of whether it applies to deemed products or future products that may be reviewed by FDA.

address the increase in underage use of ENDS products. At the time, there had been reports that ENDS use among high-school students had increased significantly since 2017.[32]

In response, JLI developed and ultimately submitted a comprehensive action plan to FDA across five pillars aimed to address youth access, appeal, and use of JUUL products. These pillars captured the following:

- Restricting the sale and distribution of flavored JUUL products;
- Limiting online accessibility;
- Strengthening retailer compliance to prevent youth access;
- Limiting marketing appeal; and
- Using innovation to solve youth use.

This action plan included thirty-nine commitments in total. The Company also created a governance structure to ensure its implementation and appointed an executive to manage the action plan, oversee its progress, and engage with FDA through quarterly updates and related communications. JLI provided three quarterly updates to FDA through July 2019, which tracked the progress of each commitment and provided additional information as they were completed. Some of these commitments included the following:

- Stopping the sale and distribution of NTM flavored JUUL products (Cucumber, Creme, Fruit, and Mango) to traditional retail;
- Adopting more stringent product-quantity limits for JUUL.com (the only authorized online retailer for JUUL products) to reduce the potential for social sourcing;
- Adopting two-factor authentication for sales on JUUL.com, which requires potential purchasers to input a unique code sent to their mobile phone to verify their identity even before entering JLI's age-verification process;
- Requiring potential online purchasers to provide a real-time selfie to match the individual's face against their uploaded ID, which is verified by a third party;[33]

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[32] *See, e.g.*, Bill O'Leary, FDA Chief Calls Youth Use of Juul, Other E-cigarettes an 'Epidemic,' Washington Post (Sept. 12, 2018) ("The latest data, not yet published, show a 75 percent increase in e-cigarette use among high school students this year compared to 2017.").

[33] The automated, multi-step age-verification process for purchases on JUUL.com provides two methods to verify the consumer's age (21+) and identity: (i) the consumer may provide personal information, including a partial social-security number, which is then cross checked by a third party against publicly available records and databases; or (ii) the purchaser may upload their government-issued ID, which is then verified by a third party.

- Launching a third-party audit of its online age-verification system to ensure its effectiveness and implement enhancements as needed;

- Instituting a "no sales list" for retailers that violate the Company's authorized reseller policy, including if the brick-and-mortar retailer illicitly sells JUUL products through a website;

- Penalizing retailers that fail FDA's compliance-check inspections and receive a Civil Monetary Penalty (CMP), up to a potential sales ban for multiple violations;

- Expanding its internal secret-shopper program to at least 2,000 checks to assess retailer compliance with federal age-verification requirements and JLI's product-quantity restrictions;

- Exiting social-media platforms and retaining a Twitter account only for non-promotional corporate communications; and

- Establishing a track-and-trace system for JUUL products, with an online-reporting portal, to help identify which retailers were potentially selling JUUL products to youth and take appropriate action.

JLI's November 2018 action plan was developed to address youth use of JUUL products specifically, focusing on access and appeal. But the Company remained concerned that, absent category-wide measures, underage use of ENDS products, including JUUL products, was not going to decline. In the summer of 2019, JLI undertook additional underage-prevention measures to further restrict access and use of JUUL products and help drive category-wide change for all ENDS.

This included the roll-out of its Retail Access Control Standards (RACS) program for retailers of JUUL products. RACS is based on a POS solution that automates the transaction from beginning to end, ensuring the retailer validates the age of the purchaser (21+) and limits the amount of product that can be purchased to reduce the potential for social sourcing. In short, a RACS-compliant POS system:

- Automatically requires the scanning of a government-issued ID to verify age and ID validity (i.e., the ID has not expired);

- Automatically limits the amount of product that can be purchased in a single transaction;[34] and

- Automatically integrates the sales transaction to prevent manual override by the retail salesclerk.

[34] JLI's current product-quantity limit at retail is 1 JUUL device and 4 JUULpod packages per transaction.

If an ID is not scanned to verify age and validity, the system will not allow the transaction to be completed. If the purchaser's ID reflects an age younger than 21 or is expired, the system will not allow the transaction to be completed. And if the purchase exceeds the product-quantity limits, the system will not allow the transaction to be completed.

The retailer either can update its current POS system to meet RACS or invest in a new POS system that complies with RACS. For the latter, the Company has partnered with multiple POS technology providers to develop a solution across retailer types, including smaller, independent shops. To date, RACS technologies have been implemented at over 10,000 retail outlets, and JLI will continue to work with its retailer partners and national POS vendors to expand RACS across stores that sell JUUL and other tobacco products.

To continue to improve retailer compliance, JLI also implemented a "three-strikes policy" under which repeat non-compliant retailers will not be authorized to sell JUUL products for at least one year. Previously, the Company assessed retailer compliance across multiple metrics and instituted varying penalties for failures: (i) retailers that receive an FDA CMP; (ii) retailers that fail a JLI secret-shop for age verification; and (iii) retailers that fail a JLI secret-shop for product-quantity restrictions.

Now, JLI consolidates these violations into one reporting and penalty structure. While continuing to track the three metrics referenced above, after three cumulative violations within a calendar year, the Company places the retailer on its "no-sales list" and cuts off sales for one year. We believe this three-strikes policy sends a clear message to our retailers: Demonstrate that you can prevent underage access or you cannot sell JUUL products.

In addition, since September 2019, we voluntarily stopped product advertising through broadcast (e.g., television; radio), print, and digital channels; stopped the sale and distribution of all non-tobacco- and non-menthol-flavored JUUL products before FDA issued its January 2020 final guidance; and committed to not lobby the Administration on FDA's flavor policy.

We will continue to develop new and innovative measures, driven by data, to address underage access and appeal of our products and work with other stakeholders, including this Congress, to develop effective tobacco-control strategies.

3. In addition to the Customs and Border Patrol, does your company have a direct line of communication with other law enforcement entities for reporting illicit products?

a. If so, has information that your company has provided to law enforcement resulted in criminal enforcement actions?

Response: JLI maintains a broad, cross-functional program focused on enforcement of illegal, third-party activities relating to JUUL products. This includes active enforcement against illicit black-market products — such as counterfeit JUUL products, illegal products

that are designed to be "compatible" with JUUL products, and JUUL products diverted from international markets and imported into the United States — and against illicit sellers of JUUL products — such as retailers that have been banned from selling JUUL products because of non-compliance or online resellers of JUUL products.[35] The Company's Brand Protection and Intellectual Property teams lead these targeted enforcement activities against manufacturers, importers, distributors, and retailers for selling illicit products.

Such enforcement is critical because illicit black-market products may present additional health and safety risks to consumers and may be sold in channels that contribute to underage access. These products are manufactured under unknown quality controls and standards and with unknown ingredients and likely come to market without any product characterization and manufacturing-release testing. For JUUL products specifically, we have seen a rapid proliferation of illicit counterfeit and compatible products given the Company's voluntary actions to restrict the availability of its own products.

For example, after JLI suspended the sale and distribution of NTM flavored JUUL products in November 2018, hundreds of different products, all of them likely in violation of FDA regulation and policy, came to the market in various flavors and packaging that appeared to be targeted to minors. As discussed above, the largest manufacturer of compatible products, Eonsmoke, received a Warning Letter from FDA in October 2019 for selling nearly 100 different products illegally without marketing authorization. JLI has dedicated extensive resources to combat the marketing of illegal compatible products, particularly because they often are sold online without any age verification and in flavors and packaging that may appeal to minors.

Through our Brand Protection team, we have engaged with law enforcement entities, in addition to the Customs and Border Protection (CBP), to provide education on illicit product types and points of entry, develop evidence to support enforcement actions, and coordinate on seizures, raids, and other programs to remove illicit products from the market. Generally, engagement and enforcement activities focus on two types of illicit products (counterfeit and diverted products) across three distinct areas of the supply chain (production, distribution, and retail).

Most counterfeit products are manufactured in China and imported into the United States through various points of entry. Our Brand Protection team has engaged with attachés from the Department of Homeland Security (DHS) at posts in or around China to help identify illicit manufacturers. The Company also has conducted or supported raids of these facilities with local foreign governments. Moreover, the Brand Protection team has developed training and education programs for customs enforcement, including federal and state authorities, to help identify illicit products as they enter U.S borders.

[35] JUUL.com is the only authorized retailer of JUUL products online. Through JLI's reseller policy, brick-and-mortar retailers that carry JUUL products are prohibited from also selling products online. The Company also actively seeks product takedowns from third-party e-commerce platforms and resellers, such as eBay and Alibaba.

At retail, JLI conducts routine market surveys and evidence purchases to identify outlets that sell counterfeit and diverted products. If retailers are engaged in such activities, the Company's Brand Protection team issues cease-and-desist letters that require the retailer, among other things, to stop the sale of illicit product and identify its upstream supplier. Violative retailers also are placed on JLI's "no-sales list" and are restricted from receiving authorized JUUL products from either JLI or its distributors.

In 2019, the Company issued approximately 850 cease-and-desist letters with a compliance rate of about 75%. JLI then provides the names of non-compliant retailers to local law enforcement for additional action, and the Company has shared lists of retailers that have received cease-and-desist letters for carrying counterfeit or diverted product with FDA's Office of Criminal Investigations.

Beyond its own activities, JLI has worked with state and local law enforcement authorities to establish enforcement investigations against distributors and retailers of illicit products. Typically, the Brand Protection team builds cases through its own investigations and evidence-buys and then provides the information, including the names of retailers and upstream distributors, to law enforcement for prosecution.

Since 2019, the Company has supported dozens of cases brought by state and local law enforcement. This includes product seizures, raids, and prosecutions against illicit distributors, retailers, and resellers of black-market product, as well as enforcement by local tax authorities. Even in instances that do not result in a prosecution, JLI will take its own enforcement action, including issuing cease-and-desist letters, as noted above, and even initiating litigation.

Similar to the illicit cigarette trade in years prior, the growth and success of the ENDS category will result in an increase in the manufacturing, importation, and sale of illegal black-market products. JLI will continue its own programmatic enforcement activities against sources of these illicit products and coordinate and support federal, state, and local law enforcement entities to clear the market of these potentially dangerous products.

4. What does your company do to ensure the safety of the supply chain for your ENDS products?

Response: Ensuring the quality of JUUL products across the supply chain is paramount to provide our adult consumers with a product that has been appropriately tested and controlled and consistently manufactured from end-to-end. In that regard, JLI has established a robust Quality System that covers the entire manufacturing process for JUUL products, including ingredient testing, production, product release, and distribution.

While FDA is in the process of initiating rulemaking on the equivalent of Good Manufacturing Practice (GMP) requirements for tobacco products (referred to as "Tobacco Product Manufacturing Practice requirements" or "TPMP requirements"), the Company has borrowed concepts from GMP for pharmaceutical and medical device products and incorporated similar requirements into its quality program. This includes certification of

JLI's contract manufacturers against international manufacturing standards, audits of its suppliers, in-process product testing and batch-release testing on final product, and investigations for manufacturing or product deviations that could impact quality.

The nicotine-containing e-liquid formulation in JUUL products is filled in the United States. Each e-liquid supplier is assessed or certified against ISO 9001, which specifies requirements for a quality management system and ensures that products are manufactured reliably and consistently in accord with internal and/or regulatory requirements. E-liquid production and filling also are conducted in ISO-certified clean rooms. Moreover, the Company, through its contract manufacturers, performs chemical testing on every batch of e-liquid before release and further processing. While produced by a contract manufacturer, JLI maintains on-site quality supervision and is responsible for the approval and release of the bulk e-liquid.

JUUL devices are manufactured overseas and in the United States, and each manufacturing facility is certified against ISO 13485, an international manufacturing standard for medical devices which governs the design and manufacture of the products to ensure quality. Each JUUL device is inspected before leaving our manufacturing facilities, undergoing 100% functional testing under simulated-use conditions before and after charging. The Company also conducts reliability testing to simulate the effects of stress under actual or potential use over time, including impact and drop testing.

In addition, JLI maintains specific controls for its suppliers across the supply chain. This includes the following:

- Agreements requiring strict and precise testing on the component products that suppliers provide our downstream manufacturers;

- In-person site visits and recurring audits of supplier facilities to ensure compliance with our Quality System;

- Approved vendor lists to ensure only those suppliers that meet our quality standards are permitted to enter the supply chain; and

- Agreements with finished-product suppliers requiring strict adherence to our quality standards.

The Company also drives all automated equipment validations and process changes at its contract manufacturing facilities and, as noted above, maintains on-site quality supervision of production and product release.

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